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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,128	08/29/2005	Bronislava Gedulin	0402US-UTL	7370

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Intellectual Property Department
Amylin Pharmaceuticals, Inc.
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EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
09/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,128	GEDULIN ET AL.	
	Examiner	Art Unit	
	RUIXIANG LI	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-12,14-30 and 32* is/are pending in the application.

4a) Of the above claim(s) *7 and 15-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8-12,14,22-30 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

Applicant's amendment filed on 06/10/2009 has been entered. Claims 1-3, 5-12, 14-30, and 32 are pending. Claims 1-3, 5, 6, 8-12, 14, 22-30, and 32 are under consideration. Claims 7 and 15-21 are withdrawn from consideration.

Withdrawn Objections and/or Rejections

The rejection of claims 27-29 under 35 U.S.C. 112, second paragraph, is withdrawn in view of amended claims.

The rejection of claims 1-3, 5, 6, 8-12, 22-30, and 32 under 35 U.S.C. 112, first paragraph for written description is withdrawn.

Continuing Data

The filing data of PCT/US03/18657 provided by Applicants in is not consistent with PTO records. The FORM PTO-1390 filed by Applicants on 12/14/2004 indicates that the international filing date of PCT/US03/18657 is April 24, 2003, whereas the PTO records indicate that the international filing date of PCT/US03/18657 is 06/13/2003. Moreover, the oath/Declaration filed on 08/29/2005 indicates that 10/518,128 was filed on December 14, 2004, whereas the PTO records indicate that the filing or 371(c) date of 10/518,128 is 08/29/2005.

It's noted that Applicants have not address the issue, which is noted in the previous office action.

Claim Rejections Under 35 U.S.C.§112, 1st Paragraph (New Matter)

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 1-3, 5, 6, 8-12, 30, and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim 1 recites a limitation, "wherein said active fragment comprises amino acids 22-26 of the amino acid sequence set out in SEQ ID NO: 2", which introduces new matter. There is no support for such a limitation in the application as filed.

Applicants argue that the disclosure of a fragment of PYY consisting of amino acids 22-26 of PYY (i.e. SEQ ID NO: 2) as a fragment that possesses, e.g., PYY receptor binding affinity was within the purview of the skilled artisan by virtue of, at least, Balasubramaniam et al. Applicants argue that Balasubramaniam et al disclose that the sequence 22-26 [of PYY] plays a crucial role in receptor recognition. Applicants argue

that the skilled artisan would understand that PYY fragments comprising, e.g., amino acids 22-26, constitute "PYY agonists" comprising "an active fragment of PYY".

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. Replacing the identified material incorporated by reference with the actual text is not new matter. See 37 CFR 1.57 and MPEP § 608.01(p) for Office policy regarding incorporation by reference. However, the material—"wherein said active fragment comprises amino acids 22-26 of the amino acid sequence set out in SEQ ID NO: 2" is not incorporated by reference and uniquely identified in the application as filed. Thus, it introduces new matter. The issue here is not whether a PYY agonist is known in the prior art; rather it is whether the specification has support for the limitation.

Moreover, the specification defines PYY as a peptide YY polypeptide obtained or derived from any species, and defines PYY agonist as any compound which elicits an effect of PYY to protect from or reduce colon injury associated with inflammatory bowel disease or ulcerative colities *and* which binds specifically in a Y receptor assay or in a competitive binding assay (page 10). The specification does not specifically defines a PYY agonist as one comprising amino acids 22-26 of SEQ ID NO: 2, whereas the cited prior art does not teach PYY agonists in the context of eliciting an effect to protect from or reduce colon injury associated with inflammatory bowel disease or ulcerative colities. Accordingly, the new matter is maintained.

(iii). Claims 1-3, 5, 6, 8-12, and 30-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating, ameliorating, or protecting from an intestinal damage, comprising peripherally administering a pharmaceutically active formulation of PYY or PYY(3-36) to a human to treat or alleviate the intestinal damage, does not reasonably provide enablement for a method of preventing an intestinal damage. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

With respect to preventing an intestinal damage, Applicants argue that the specification discloses that the results of working example titled Example 1 indicates that PYY or a PYY agonist may be used to protect from colon injury. This is not persuasive because working example 1 shows the reduction of colon injury of animal model for inflammatory bowel disease using PYY[3-36]; it does not show that PYY or PYY agonists may be used to prevent an intestinal damage associated with a condition, such as inflammatory bowel disease.

Claim Rejections Under 35 U.S.C.§102 (b)

(i). The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(ii). Claims 1, 2, 5, 10-12, 22-30, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997).

Balasubramaniam teaches PYY and a pharmaceutical formulation comprising PYY (columns 15-16). The human PYY comprises amino acids 22-26 of SEQ ID NO: 2 of the present invention and the amino acid residues recited in claims 23-29 (column 2). Balasubramaniam teaches treating gastrointestinal disorders that are associated with excess intestinal electrolyte and water secretion as well as decreased absorption, such as infectious or inflammatory diarrhea, or diarrhea resulting from surgery (column 16) comprising administering to a mammal, such as a human (column 6, lines 43-47). Inflammatory diarrhea includes Crohn's disease (column 7), a form of inflammatory bowel disease. The intestinal damage caused by these gastrointestinal disorders necessarily comprises a morphological damage, such as an ulceration and those listed in claims 30 and 32. Moreover, since the subject recited in claim 1 is a human, which is the same as taught by Balasubramaniam, the administering of PYY or a PYY agonist appears to be capable of exhibiting the effect recited in the preamble of claim 1.

Balasubramaniam also teaches that PYY inhibits gut motility and blood flow, attenuates basal and secretagogue-induced intestinal secretion in humans. Balasubramaniam further teaches that PYY plays a physiological role in regulating intestinal secretion and absorption, serving as natural inhibitors of diarrhea (column 1, lines 35-54; column 6, lines 43-67). Balasubramaniam further teaches that the compounds can be

administered orally or parenterally (intravenously or subcutaneously) (column 14). The daily dose in the case of oral administration is typically in the range of 0.1 to 100 mg/kg body weight, and the daily dose in the case of parenteral administration is typically in the range of 0.001 to 50 mg/kg body weight (column 16).

Accordingly, the teachings of Balasubramaniam meet the limitations of claims 1, 2, 5, 10-12, 22-30, and 32.

Response to Applicants' argument

Applicants argue that nowhere in the cited reference is there is a specific recitation with regard to "a morphological damage" in the recited reference, not to any of the damage recited in claims 30 and 32. Applicants argue that none of the gastrointestinal disorders disclosed in the cited reference is taught to necessarily comprise an ulceration.

Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. First, Balasubramaniam teaches PYY and a pharmaceutical formulation comprising PYY (columns 15-16). The human PYY comprises amino acids 22-26 of SEQ ID NO: 2 of the present invention and the amino acid residues recited in claims 23-29 (column 2). Balasubramaniam teaches treating gastrointestinal disorders that are associated with excess intestinal electrolyte and water secretion as well as decreased absorption, such as infectious or inflammatory diarrhea, or diarrhea resulting from surgery (column 16) comprising administering to a mammal, such as a human (column 6, lines 43-47). Inflammatory diarrhea includes Crohn's disease (column 7), a

form of inflammatory bowel disease. The intestinal damage caused by these gastrointestinal disorders necessarily comprises a morphological damage, such as an ulceration and those listed in claims 30 and 32. Second, the subject recited in claim 1 is a human, which is the same as taught by Balasubramaniam, the administering of PYY or a PYY agonist appears to be capable of exhibiting the effect recited in the preamble of claim 1.

Furthermore, there is no evidence on the record showing that an intestinal damage associated with, for example, inflammatory bowel disease does not comprise an ulceration. In fact, the histologic features of inflammatory bowel diseases such as ulcerative colitis or Crohn's disease comprise ulcer as evidenced by U.S. patent No. 5,214,066 (column 7, lines 1-7; column 1, lines 49-51).

Claim Rejections Under 35 U.S.C.§103 (a)

(i). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(ii). Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Balasubramaniam (U. S. Patent No. 5,604,203, Feb. 18, 1997), as applied to claims 1,

2, 5, 10-12, and 22-32 above, and further in view of Dumont et al. (Brain Res. Mol. Brain Res. 26: 320-324, 1994).

Balasubramaniam teaches a method of treating an intestinal damage comprising administering a pharmaceutically active formulation of PYY to a human subject as applied to claims 1, 2, 5, 10-12, and 22-32 above.

Balasubramaniam fails to teach the method of claim 14, comprising administering PYY[3-36].

Dumont et al. teach a PYY agonist, PYY[3-36] that binds PYY receptors (see Abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use PYY[3-36] in the method of treating a gastrointestinal disorder, such as Crohn's disease (a form of inflammatory bowel) as taught by Balasubramaniam with a reasonable expectation of success. One would have been motivated to do so because Balasubramaniam teaches PYY and PYY functional analogs can be used to treat a gastrointestinal disorder, such as Crohn's disease (first paragraph of column 7), whereas PYY [3-36] that binds to PYY receptors is expected to have the similar effect in treating a gastrointestinal disorder, such as Crohn's disease.

Response to Applicants' argument

Applicants argue that Balasubramaniam fail to teach a method of treating intestinal damage comprising administering a pharmaceutically active of PYY or a PYY agonist polypeptide as instantly claimed. Applicants argue that Dumont fails to cure the deficiencies of the teachings of Balasubramaniam. Applicants' argument has been fully considered, but is not deemed to be persuasive for the reasons set forth above.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

/Ruixiang Li/
Primary Examiner, Art Unit 1646

Ruixiang Li, Ph.D.
August 30, 2009